

PATENT

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Applicants: Sheng C. Lou, et al.

Serial No.: (not yet assigned)

*Divisional of application Serial No.: 09731,126;
filed 12/6/00; Examiner J. Parkin; Group Art Unit
1648*

Filed: November 17, 2003

Title: MONOCLONAL ANTIBODIES TO
HUMAN IMMUNODEFICIENCY VIRUS
AND USES THEREOF

Attorney Docket No.: 6755.US.D1

Group Art Unit: (not yet assigned)

EXPRESS MAIL NO.: EV314259884US

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INFORMATION DISCLOSURE STATEMENT

MS Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The following information is submitted, pursuant to 37 CFR §§1.97-1.98 in accordance with Applicant's duty of disclosure under 37 CFR §1.56. This submission is not intended to constitute an admission that any patent, publication or other information cited herein is "prior art" as to the invention claimed. In accordance with 37 CFR §§1.97(g)-(h), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that other material information as defined by 37 CFR §1.56(a) exists.

Applicants submit herewith Form PTO-1449 listing the references known to them. Applicants respectfully request that the Examiner (1) initial each reference listed on the enclosed Form PTO-1449 indicating that the Examiner has considered and made those references of record in this application and (2) return a copy of the initialed Form PTO-1449 to Applicants. Copies of references were previously submitted in U.S. Serial No. 09/731,126, filed December 6, 2000, from which this divisional application claims priority.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits under 37 CFR §1.97(b). Accordingly, no charge is required.

Respectfully submitted,
Sheng C. Lou, et al.

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DATE: November 17, 2003

SHEET 1 of 6

Form PTO - 1449 (Modified)

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE (Modified) PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) (37 CFR 1.98 (b))	ATTY. DOCKET NO. 6755.US.D1	SERIAL NO.
	APPLICANT(S) Sheng C. Lou, et al.	
	FILING DATE November 17, 2003	GROUP

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		PATENT NUMBER	ISSUE DATE	INVENTOR	CLASS	SUB CLASS	FILING DATE
	A1	5612453 A	03/18/1997	Wolf Hans, et al.			

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

		DOCUMENT NUMBER	PUBLIC-ATION DATE	COUNTRY OR PATENT OFFICE	CLASS	SUB CLASS	TRANS- LATION YES NO
	B1	9014358 A	11/29/1990	PCT			
	B2	034561 A	12/13/1989	EPO			
	B3	19727943	09/24/1998	DE			
	B4	9840744	09/17/1998	PCT Abstract			

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

	C1	Niedrig, M. et al., "Characterization of Murine Monoclonal Antibodies Directed Against the core Proteins of Human Immunodeficiency Virus Types 1 and 2," Journal of Virology, 65/8:4529-4533 (1991)
	C2	Minassian, A.A, et al., "Monoclonal Antibodies Against Human Immunodeficiency Virus HIV Type 2 Core Proteins Cross-Reactivity With HIV Type 1 and Simian Immunodeficiency Virus," Proceedings of the national Academy of Sciences of the United States, 6/18:6939-6943 (1988)
	C3	Zolla-Pazner, Susan, et al., "The Implication of Antigenic Diversity for Vaccine Development," Immunology Letters, 66/1-3: 159-164 (1999-03)

EXAMINER	DATE CONSIDERED
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6755.US.D1

INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

APPLICANT(S)

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GROUP

(Use several sheets if necessary)

(37 CFR 1.98 (b))

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		PATENT NUMBER	ISSUE DATE	INVENTOR	CLASS	SUB CLASS	FILING DATE
	A1	4,886,742	12-12-89	Kortright, et al.			
	A2	4,888,290	12-19-89	Kortright, et al.			
	A3	5,173,399	12-22-92	Mehta, et al.			
	A4	5,210,181	05-11-93	Butman, et al.			
	A5	5,514,541	05-07-96	Butman, et al.			
	A6	5,731,189	03-24-98	Zolla-Pazner, et al.			

FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

		DOCUMENT NUMBER	PUBLIC- ATION DATE	COUNTRY OR PATENT OFFICE	CLASS	SUB CLASS	TRANS- LATION
	B1	EP 0519866A1	12-23-92	EPO			YES NO
	B2	WO 93/21346	10-28-93	WO			

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

C1	Allain, et al., <u>The Lancet</u> , Serological Markers in Early Stages of Human Immunodeficiency Virus Infection in Haemophiliacs, ii:1233-1236 (1986)
C2	Barin, et al., <u>Science</u> , Virus Envelope Protein of HTLV-III Represents Major Target Antigen for Antibodies in AIDS Patients, 228:1094-1096 (1985)
C3	Barin, et al., <u>The Lancet</u> , Serological Evidence for Virus Related to Simian T-Lymphotropic Retrovirus III in Residents of West Africa, 2:1387-1389 (1985)
C4	Bowen, et al., <u>Annals of Internal Medicine</u> , Transmission of Human Immunodeficiency Virus (HIV) by Transplantation: Clinical Aspects and Time Course Analysis of Viral Antigenemia and Antibody Production, Ann. Of Int. Med. 108:46-48 (1988)
C5	R.H. Burdon and P.H. van Knippenberg, eds. Vol. 15 Elsevier, Amsterdam
C6	Charneau, et al., <u>Virology</u> , Isolation and Envelope Sequence of a Highly Divergent HIV-1 Isolate: Definition of a New HIV-1 Group, 205:247-253 (1994)
C7	Clavel, et al., <u>Science</u> , Isolation of a New Human Retrovirus from West Africa Patients with AIDS, 233:343-346 (1986)
C8	Clavel, et al., <u>Nature</u> , Molecular Cloning and Polymorphism of the Human Immune Deficiency Virus Type 2, 324:691-695 (1986)

EXAMINER

DATE CONSIDERED

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

C9	Coffin, <u>Science</u> , <i>HIV Population Dynamics in Vivo: Implications for Genetic Variation, Pathogenesis and Therapy</i> , 267:483-489 (1995)
C10	Courouze, et al., <u>La Gazette de la Transfusion</u> N°155-Mars-Avril (1999)
C11	Dawson, et al., <u>The Journal of Infectious Diseases</u> , <i>Reliable Detection of Individuals Seropositive for the Human Immunodeficiency Virus (HIV) by Competitive Immunoassays Using Escherichia Coli-Expressed HIV Structural Proteins</i> , 157:149-155 (1988)
C12	Devare, et al., <u>Human Immunodeficiency Virus: Innovative Techniques, Monograph in Virology, Diagnosis and Monitoring of HIV-1 and HIV-2 Infection</u> , J.L. Melnick (ed.) Basel, Karger, vol. 18: 105-121 (1990)
C13	Euler, et al., <u>Clinical and Experimental Immunology</u> , <i>Precipitable Immune Complexes in Healthy Homosexual Men, Acquired Immune Deficiency Syndrome and the Related Lymphadenopathy Syndrome</i> , 59:267-275 (1985)
C14	Gao, F., et al., <u>Nature</u> , <i>Origin of HIV-1 in the Chimpanzee Pan Troglodytes Troglodytes</i> , 397:436-441 (1999)
C15	Gonda, et al., <u>Science</u> , <i>Sequence Homology and Morphologic Similarity of HTLV-III and Visna Virus, a Pathogenic Lentivirus</i> , 277:177-179 (1985)
C16	Goudsmit, et al., <u>The Lancet</u> , <i>Expression of Human Immunodeficiency Virus Antigen (HIV-Ag) In Serum and Cerebrospinal Fluid During Acute and Chronic Infection</i> , ii:177-180 (1986)
C17	Griffith, et al., <u>Journal of Clinical Microbiology</u> , <i>Stability of Free and Complexed Human Immunodeficiency Virus Type 1 and Antigen at 4 °C and at Room Temperature</i> , 33:1348-1350 (1995)
C18	Gupta, et al., <u>New England Journal of Medicine</u> , <i>Correspondence: Circulating Immune Complexes in AIDS</i> , 310:1530-1531 (1984)
C19	Gurtler, et al., <u>Journal of Virological Methods</u> , <i>Reactivity of Five Anti-HIV-1 Subtype O Specimens with Six Different Anti-HIV Screening ELISAs and Three Immunoblots</i> , 51:177-184 (1995)
C20	Gurtler, et al., <u>Journal of Virological Methods</u> , <i>Reduction of the Diagnostic Window with a New Combined p24 Antigen and Human Immunodeficiency Virus Antibody Screening Assay</i> , 75:27-38 (1998)
C21	Gurtler, et al., <u>Journal of Virological Methods</u> , <i>A New Subtype of Human Immunodeficiency Virus Type 1 (MVP-5180) From Cameroon</i> , 68:1581-1585 (1994)
C22	Guyader, et al., <u>Nature</u> , <i>Genome Organization and Transactivation of the Human Immunodeficiency Virus Type 2</i> , 326:662-669 (1987)
C23	Haesevelde, et al., <u>Journal of Virology</u> , <i>Genomic Cloning and Complete Sequence Analysis of a Highly Divergent African Human Immunodeficiency Virus Isolate</i> , 68:1586-1596 (1994)

EXAMINER**DATE CONSIDERED**

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C24	Hunt, et al., <i>AIDS Research and Human Retroviruses, Envelope Sequence Variability and Serologic Characterization of HIV Type 1 Group O Isolates from Equatorial Guinea</i> , 13:995-1005 (1997)
C25	Kageyama, et al., <i>Journal of Virological Methods, An Improved Method for the Detection of HIV Antigen in the Blood of Carriers</i> , 22:125-131 (1988)
C26	Kanki, et al., <i>Science, New Human T-Lymphotropic Retrovirus Related to Simian T-Lymphotropic Virus Type III (STLV-III_{AGM})</i> , 232:238-243 (1986)
C27	Kanki, et al., <i>Science, Human T-Lymphotropic Virus Type 4 and the Human Immunodeficiency Virus in West Africa</i> , 236:827-831 (1987)
C28	Karush, F. In <i>Comprehensive Immunology</i> , ed. R.A. Good, S.B. Day, <i>The Affinity of Antibody: Range, Variability and the Role of Multivalence</i> , 5:85-116 (1978)
C29	Kenny, et al., <i>The Lancet, HIV Antigen Testing</i> , 1(8532):565-566 (1987)
C30	Kessler, et al., <i>JAMA, Diagnosis of Human Immunodeficiency Virus Infection in Seronegative Homosexuals Presenting with an Acute Viral Syndrome</i> , 258:1196-1199 (1987)
C31	Ly, et al., <i>Journal of Clinical Microbiology, Contribution of Combined Detection Assays of P-24 Antigen and Anti-Human Immunodeficiency Virus (HIV) Antibodies in Diagnosis of Primary HIV Infection by Routine Testing</i> , 38(6): 2459-2461 (2000)
C32	Mariuzza, et al., <i>Rev. Biophys. Chem., The Structural Basis of Antigen-Antibody Recognition</i> , 16:139-159 (1987)
C33	Mathiesen, et al., <i>Journal of Virological Methods, Acid Hydrolysis of Serum Samples to Increase Detection of HIV Antigen</i> , 22:143-148 (1988)
C34	Mauclere, P. <i>AIDS, Serological and Virological Characterization of HIV-1 Group O Infection in Cameroon</i> , 11:445-453 (1997)
C35	Mellors, et al., <i>Science Prognosis in HIV-1 Infection Predicted by the Quantity of Virus in Plasma</i> , 275:1167-1170 (1996)
C36	Meyerhans, et al., <i>Cell, Temporal Fluctuations in HIV Quasispecies in Vivo are not Reflected by Sequential HIV Isolations</i> , 58:901-910 (1989)
C37	Montagnier, et al., <i>Virology, Identification and Antigenicity of the Major Envelope Glycoprotein of Lymphadenopathy-Associated Virus</i> , 144:283-289 (1985)

EXAMINER

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EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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C38	Mulder, et al., <u>Journal of Clinical Microbiology</u> , <i>Rapid and Simple PCR Assay for Quantitation of Human Immunodeficiency Virus Type 1 RNA in Plasma: Application to Acute Retroviral Infection</i> , 32:292-300 (1994)
C39	Phair, <u>JAMA</u> , <i>Human Immunodeficiency Virus Antigenemia</i> , 258:p1218 (1987)
C40	Robertson, et al., <u>Nature</u> , <i>Recombination of HIV-1</i> , 374:124-126 (1995)
C41	Saag, et al., <u>Nature Medicine</u> , <i>HIV Viral Load Markers in Clinical Practice</i> , 2:625-629 (1996)
C42	Sarngadharan, et al., <u>Science</u> , <i>Antibodies Reactive with Human T-Lymphotropic Retroviruses (HTLV-III) in the Serum of Patients with AIDS</i> , 224:506-508 (1984)
C43	Schochetman, et al., <i>Aids Testing</i> , Springer-Verlag, New York, Berlin, Heidelberg
C44	Schulz, et al., <u>The Lancet</u> , <i>Envelope Gene-Derived Recombinant Peptide in the Serodiagnosis of Human Immunodeficiency Virus Infection</i> , 2:111-112 (1986)
C45	Schupbach, et al., <u>AIDS</u> , <i>Heat-Mediated Immune Complex Dissociation and Enzyme-Linked Immunosorbent Assay Signal Amplification Render p24 Antigen Detection in Plasma as Sensitive as HIV-1 RNA Detection by Polymerase Chain Reaction</i> , 10:1085-1090 (1996)
C46	Sharp, et al., <u>Biological Bulletin</u> , <i>Origins and Evolution of AIDS Viruses</i> , 196:338-342 (1999)
C47	Simmonds, et al., <u>Journal of Virology</u> , <i>Human Immunodeficiency Virus-Infected Individuals Contain Provirus in Small Numbers of Peripheral Mononuclear Cells and a Low Copy Numbers</i> , 64(2):864-872 (1990)
C48	Steindl, et al., <u>Journal of Immunological Methods</u> , <i>A Simple and Robust Method for the Complete Dissociation of HIV-1 p24 and Other Antigens from Immune Complexes in Serum and Plasma Samples</i> , 217:143-151 (1998)
C49	Stephens, et al., <u>Science</u> , <i>Equine Infectious Anemia Virus gag and pol Genes: Relatedness to Visna and AIDS Virus</i> , 231:589-594 (1986)
C50	Stute, <u>The Lancet</u> , <i>HIV Antigen In Acute HIV Infection</i> , 1(8532):p566 (1987)
C51	van Binsbergen, et al., <u>Journal of Virological Methods</u> , <i>Improved Performance of Seroconversion with a 4th Generation HIV Antigen/Antibody Assay</i> , 82:77-84 (1999)

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C52	von Sydow, et al., <u>British Medical Journal</u> , <i>Antigen Detection in Primary HIV Infection</i> , 296:238-240 (1988)
C53	Wain-Hobson, <u>Current Topics in Microbiology</u> , <i>Human Immunodeficiency Virus Type 1 Quasispecies in Vivo and Ex Vivo</i> , 176:181-193 (1992)
C54	Wall, et al., <u>The Lancet</u> , <i>HIV Antigenaemia in Acute HIV Infection</i> , 1(8532):p566 (1987)
C55	Weber, et al., <u>Journal of Clinical Microbiology</u> , <i>Reduction of Diagnostic Window by New Fourth-Generation Human Immunodeficiency Virus Screening Assays</i> , 36(8):2235-2239 (1998)
C56	Zhang, et al., <u>AIDS</u> , <i>Detection, Quantification and Sequencing of HIV-1 from the Plasma of Seropositive Individuals and from Factor VIII Concentrates</i> , 5(6):675-681 (1991)
C57	Zhu, <u>Journal of Virology</u> , <i>Evidence for Coinfection by Multiple Strains of Human Immunodeficiency Virus Type 1 Subtype B in an Acute Seroconverter</i> , 69:1324-1327 (1995)

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